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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,597	01/07/1999	JULIO PIMENTEL	ANIT0018U-US	9844

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
11/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008 and 22 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12-19,22-25 and 32-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 12-19, 22-25, and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2008 has been entered.

Amendment Entry

2. Applicant's amendment and response filed August 22, 2008 is acknowledged and has been entered. Claims 1, 16, 25, 32, and 35 have been amended. Currently, claims 1-5, 12-19, 22-25, and 32-35 are pending and are under examination.

Rejections Withdrawn

3. All rejections not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5, 12-19, 22-24 and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 lacks clear antecedent basis in reciting, "an animal" because the preamble of claim 1 recites, "A method … in mammals." Claim 1 is, therefore, confusing because it is unclear what scope of subject Applicant intends to encompass in the claim. See also claim 4.

Claim 5 is indefinite in relation to claim 1 as to the metes and bounds of the subject being claimed, because is it is unclear if the animal in claim 1 only encompasses a mammal. Claim 5 is also therefore confusing because the recitation of "an avian" is contradictory to the recitation of the animal being a "mammal" in claim 1 from which it depends.

Claim 16 lacks clear antecedent basis in reciting, "an animal" because the preamble of claim 16 recites, "A composition … in mammals." Claim 16 is, therefore, confusing because it is unclear what scope of subject Applicant intends to encompass in the claim.

Claim 32 lacks clear antecedent basis in reciting, "an animal" because the preamble of claim 32 recites, "A method … in mammals." Claim 32 is, therefore, confusing because it is unclear what scope of subject Applicant intends to encompass in the claim. See also claim 35.

Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5, 12-19, 22-25 and 32-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method and composition for decreasing weight gained in rats after feeding them food containing liposome-encapsulated anti-lipase antibody, does not reasonably provide enablement for a method and composition for decreasing weight in any and all animals and mammals after feeding them food containing liposome-encapsulated anti-lipase antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As set forth in In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The state of the prior art- the prior art of record fails to disclose a method for decreasing weight by feeding an animal liposome encapsulated anti-lipase antibody that is applicable to any and all animals.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the claimed method will work in other animals than rats or those representative of its similar size and nutrition requirement, as shown in Example 4.

The amount of direction or guidance present- appropriate guidance is provided by the specification for the claimed method to work in rats that are fed the food composition containing the liposome encapsulated anti-lipase antibody. However, the specification fails to provide guidance to enable the claimed method to function in any animal especially those having distinct sizes and nutrition requirements.

The presence or absence of working examples- working examples are provided in the specification that show a decrease in weight of rats that were fed the claimed composition at a parameter of 750 mg/kg. There are no working examples that show analogous results in other animals, which are encompassed by the broad scope of the instant claims.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the method as claimed.

The breadth of the claims- as recited, the instant claims are directed to a method of decreasing weight in animals by feeding them food containing liposome encapsulated anti-lipase antibody that is applicable to any and all animals, without any regard to the

size and nutrition requirement of all animals and mammals encompassed by the broad scope of the claims.

In this case, the specification at page 1, lines 10-13 discloses that the claimed method and composition are capable of "decreasing the amount of body weight gained after eating food" containing liposome encapsulated anti-lipase antibodies. Page 2, lines 7-10 provides that there is a decrease in the amount of body weight gained as a result of eating the food by inclusion with it liposome encapsulated anti-lipase antibodies. Page 3, lines 22-28 shows a range of amount of liposome encapsulated anti-lipase antibodies that is incorporated into the feed (25-1000 mg/kg, preferably 50-800 mg/kg) so as to allow "decreased body weight gain per unit of food" in comparison to supposed animals that were fed the same food having no liposome encapsulated anti-lipase antibodies; however, the working examples in Example 3 and Example 4 only show using 750 mg/kg of liposome encapsulated anti-lipase antibodies added in the feed for each of the dozen rats which comprises the experimental pool.

While the specification exemplifies decrease in weight of rats that have been fed a composition comprising a mixture of food and liposome-encapsulated anti-lipase antibody, the specification does not show any working examples of the claimed method whereupon decrease in weight is observed in any other animals that have been fed the same composition. The fact that the claimed method appears to work in rats is not sufficient to enable the breadth of the claimed method applied in any and all animals because a rat is not considered an acceptable animal model for all animals. The specification does not establish a direct correlation between rats and all animals which

would lead the skilled artisan to say that if the claimed method and composition work in rats then it should work in all animals to enable the breadth of the claimed method. The specification does not provide any teaching that suggests that rats can be considered an acceptable animal model for the claimed method and composition for weight reduction in humans by virtue of physiological and nutrition equivalence. Page 3 of the specification refers to the controlling of weight in mammals, avians, and any animal having a pancreas or that secretes lipase but provides no showing that the claimed method works in any of these animals. While it is not necessary to show working examples for every possible embodiment, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed method is enabled. This is not the case in the instant specification.

The mode of action and function of immunoglobulins against lipase in relation to lipase antigen, in order to decrease weight in any and all animals to enable claim 1 is not described in the specification. Throughout Applicant's disclosure, general comments on the ability of anti-lipase antibody to decrease weight gained by an animal, if included in feed, are set forth by Applicant. In page 2, lines 7-9 of the specification, Applicant discloses that the amount of body weight gained by an animal as a result of eating is **decreased** by including encapsulated anti-lipase antibodies. In page 3, lines 24-26 of the specification, Applicant discloses that the claimed invention "provides decreased body weight gain per unit of food". In Example 5 at page 5 of the specification, data appears to show effective decrease of body weight by anti-lipase antibody treated rats. In page 6 of the specification, Applicant discloses that the body

weight gained by anti-lipase antibody treated rats is “much less” than the control group. A general comment at page 1, lines 9-10 in the specification states that lipases hydrolyze a portion of dietary lipid, i.e. triacyglycerol, to fatty acids and glycerol in the gastrointestinal tract. However, nowhere in the specification describes the mode of action of the immunoglobulins against lipase antigen secreted from the gastrointestinal tract or pancreas. The specification does not provide a teaching of an interaction, i.e. binding or reaction, that takes place between immunoglobulins against lipase and lipase antigen in the gastrointestinal tract to decrease weight. The specification provides no teaching of how immunoglobulin binding to lipase, if present, causes the active site of the antigen to be inhibited. Specifically, immunological binding of anti-lipase antibody to lipase does not equate to blocking the catalytic epitope of lipase antigen. Therefore, the capability to generate anti-lipase antibodies from lipase of unknown origin that can act upon lipase antigen in any animal, to react or bind in such a way that its catalytic epitope is blocked, either in the GI tract or systemically in the plasma in order to decrease the animal's weight is an unpredictable task. Based on Applicant’s limited disclosure, one skilled in the art would not know how to make and use the claimed invention to decrease weight in any and all animals to enable claim 1, without undue experimentation.

The structure of lipase antigen from which immunoglobulins against lipase are generated from, so as to enable interspecies cross-reactivity, i.e. mammalian and avian, to decrease weight in any animal as required by claim 1, is not characterized and described in the specification. General comments on the development and generation

of anti-lipase polyclonal antibodies from avian eggs are insufficient to establish the nature or potency of the antibodies to provide interspecies cross-reactivity with lipase of any animal so to render them workable to decrease weight in any species of animal. Antibodies generated from undefined mammalian lipase sources, i.e. bovine, may not necessarily have specificity for and cross-reactivity with any other mammalian lipase species, i.e. human or avian, that are necessary for any interaction with lipase that would lead to actual reduction of weight in any and all animals. The instant specification fails to establish a correlation between lipase of humans or avians with rats, for example. Generation of antibodies that react or bind with lipase of any and all species, specifically at its catalytic site, so as to decrease weight in any animal, would appear to be an unpredictable task. Further, physiological function and metabolism between different species may account for enhanced or reduced functional potency of the immunoglobulins against lipase in reacting with a given lipase structure. Thus, one skilled in the art would reasonably conclude that even if one has knowledge in generating anti-lipase antibodies from different species such as set forth in Applicant's disclosure, some level of function of the anti-lipase antibody in decreasing weight can be affected by the structure of the lipase antigen that is endogenous to any given species. Based on Applicant's limited disclosure, one of skill in the art would not know how to make and use immunoglobulins against lipase that have a potential to exhibit absolute specificity, reactivity and functionality to lipase to cause reduction in weight of any and all animal after feed consumption, without undue experimentation.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation. The claimed method is only enabled for rats and their equivalent species in size, physiology, and nutritional requirements.

Response to Arguments

6. Applicant's arguments with respect to claims 1-5, 12-19, 22-25, and 32-35 have been considered but are moot in view of the new grounds of rejection.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

November 6, 2008